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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/598,080

09/07/2006

Kenneth Gall

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EXAMINER

MERENE, JAN CHRISTOP L

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/598,080	<b>Applicant(s)</b> GALL ET AL.	
	<b>Examiner</b> JAN CHRISTOPHER MERENE	<b>Art Unit</b> 3733	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 December 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 46-58 and 139-141 is/are pending in the application.
- 4a) Of the above claim(s) 58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 46-57 and 139-141 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. This is the initial Office action based on the 10/598,080 application filed on September 7, 2006 which is a 371 of PCT/US2006/012934 filed April 3, 2006, which claims priority to US Provisional Application 60/667,876, filed April 1, 2005.

### ***Election/Restrictions***

2. Applicant's election without traverse of Group II Species A in the reply filed on December 15, 2009 is acknowledged. Claim 58 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on December 15, 2009. Claim 58 recite "the cable member does not substantially contact the recess in the bone" which was not disclosed as belonging to Species A. As seen in Fig 2 of the specification, the cable member #204 would substantially contact bone in the recess after activation. It is believed that this claim might be directed to Species B as seen in Fig 3.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

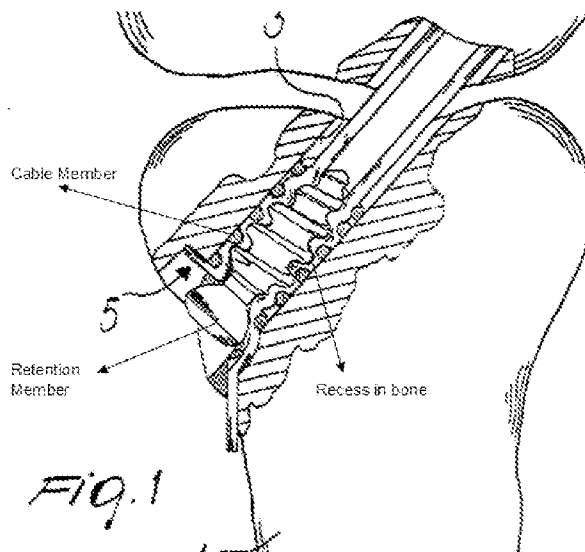
4. **Claims 46-48, 50-51, 55** are rejected under 35 U.S.C. 102(b) as being anticipated by Dovesi et al US 2002/0165547.

Regarding **Claim 46**, Dovesi discloses a method comprising:

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inserting a cable member (#6) into a recess in a bone (see Fig below as well as Figs 2-4);

inserting a retention device (#7) into the recess, the retention device containing a shape memory material; and activating the shape memory material (as seen in Fig below and see paragraph 25-26, 30).



Regarding **Claim 47**, Dovesi discloses fixing the cable member to the recess (see Fig above and paragraphs 26-27).

Regarding **Claim 48**, Dovesi discloses creating the recess in the bone (as seen in Fig above where a recess is created).

Regarding **Claim 50**, Dovesi discloses creating compacting bone tissue surrounding the recess in the bone (see Fig above where a recess is created where the bone tissue surrounded the recess had to be compacted in order to create the recess).

Regarding **Claim 51**, Dovesi discloses creating the cable member is selected from an animal tissue, a synthetic fiber, a natural fiber, a polymer, a metallic wire, a bundle, and a composite (as seen in Fig 2-4 and paragraph 30).

Regarding **Claim 55**, Dovesi discloses the inserting the cable member operation precedes the inserting the retention device operation (see paragraph 25).

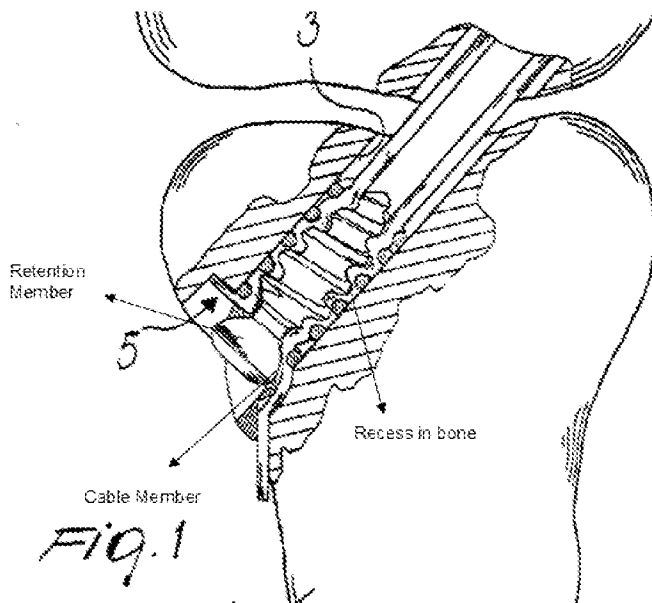
5. **Claims 46, 51** are rejected under 35 U.S.C. 102(b) as being anticipated by Dovesi et al US 2002/0165547.

Regarding **Claim 46**, Dovesi discloses a method comprising:

inserting a cable member (T, see paragraph 26) into a recess in a bone (see Fig below as well as Figs 2-4);

inserting a retention device (#5) into the recess, the retention device containing a shape memory material; and activating the shape memory material (as seen in Fig below and see paragraph 25-26, 30).

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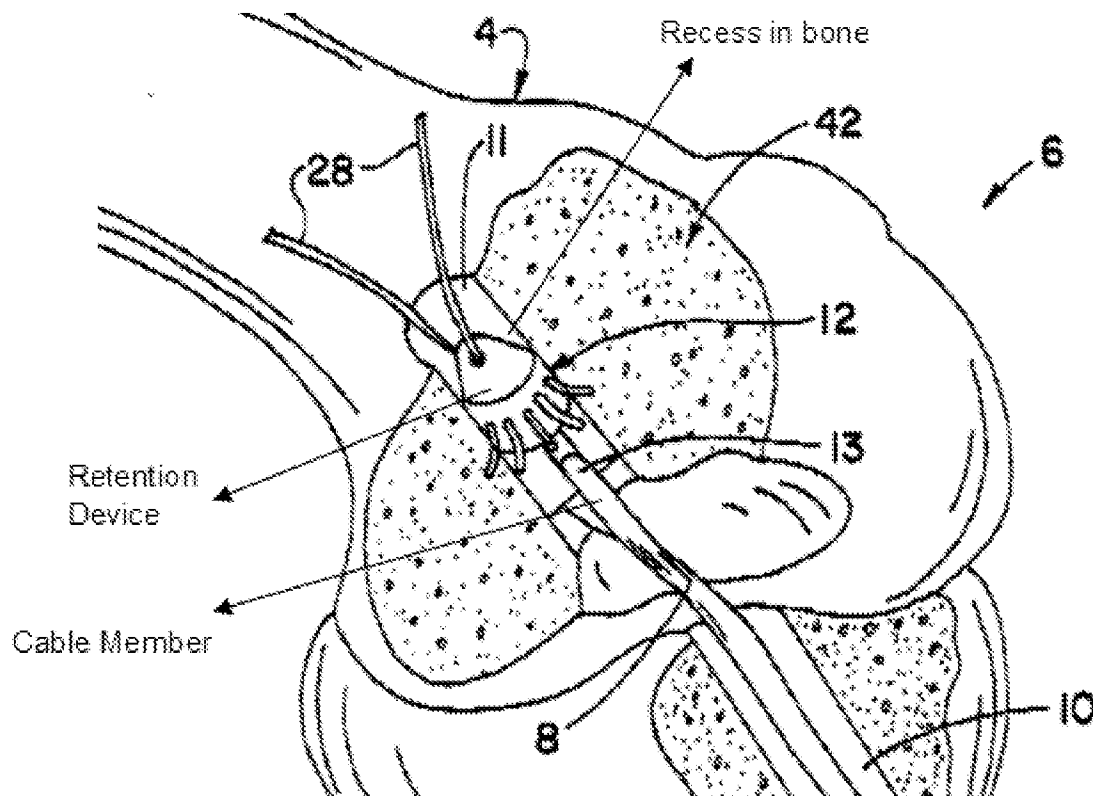
Regarding **Claim 51**, Dovesi discloses creating the cable member is selected from an animal tissue, a synthetic fiber, a natural fiber, a polymer, a metallic wire, a bundle, and a composite (see paragraph 1, 26, where the cable member can be a natural or synthetic).

6. **Claims 46, 48, 56** are rejected under 35 U.S.C. 102(b) as being anticipated by Li US 5,505,735.

Regarding **Claim 46**, Li discloses a method comprising:

inserting a cable member (#8) into a recess in a bone (see Fig below);

inserting a retention device (#12) into the recess, the retention device containing a shape memory material; and activating the shape memory material (see Col 7 lines 20-30, where the retention device has barbs made out of nitinol, a shape memory material).



Regarding **Claim 48**, Li discloses creating the recess in the bone (as seen in Fig above where a recess is created).

Regarding **Claim 56**, Li discloses inserting the cable member operation is performed simultaneously with the inserting of the retention device operation (see Fig above in claim 46, Fig 2, Col 8 lines 30-53, wherein the retention device has a hole for sutures #28 and a hole #30 for the cable member, where the sutures is pulled, wherein inserting the cable member and retention member is simultaneously performed).

Regarding **Claim 54, 139**, Li discloses activating comprises an operation on the shape memory material from heating from the bone (see Col 7 lines 20-30 and Fig above, where the retention device contains nitinol, where an inherent property of nitinol is it's reaction to temperature, in particular body temperature). (The examiner notes

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Sherman US 5,728,098 teaches that nitinol has a transformational temperature range between room temperature and the human body, Col 4 lines 1-6, where heat from within the bone would interact with the nitinol).

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to



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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. **Claim 49-50** is rejected under 35 U.S.C. 103(a) as being unpatentable over Dovesi et al US 2002/0165547 in view of Rieser et al US 2001/0041937.

Dovesi discloses the claimed invention as discussed above, where a recess is formed in the bone but does not disclose dilating the recess.

Reser discloses creating a recess through a combination of drilling and/or bone dilation (see paragraph 39).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to dilate the recess of Dovesi in view of Rieser because it applies a known technique to a known method ready for improvement to yield predictable results of forming a recess in bone, where when dilating the recess, bone tissue would be compacted.

11. **Claim 52** is rejected under 35 U.S.C. 103(a) as being unpatentable over Dovesi et al US 2002/0165547 in view of Chan US 2002/0188298.

Dovesi discloses the claimed invention as discussed above, where the cable member can be natural or synthetic but does not disclose that it is made from human soft tissue.

However, Chan discloses a similar method with a cable member (L) and a retention device (#1 as seen in Fig 2), wherein the cable member is made from a human donor or the patient itself (see paragraph 8-9), wherein human tissue is a known

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material used for ligament construction/cable member construction (see paragraphs 6-9).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the cable member of Dovesi to be made out of human soft tissue in view of Chan because human tissue is a known material used for ligament construction/cable member construction. It would have been further obvious to one having ordinary skill in the art at the time the invention was made to have the cable member be made out of human soft tissue, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

12. **Claim 53** is rejected under 35 U.S.C. 103(a) as being unpatentable over Dovesi et al US 2002/0165547 in view of Brulez et al US 2006/0136057.

Dovesi discloses the claimed invention as discussed above, where the cable member can be natural or synthetic but does not disclose initiating a polymerization of a monomer solution.

However, Brulez discloses the use of ligaments graft/cable member, (see paragraph 1), where it initializes a polymerization of a monomer solution (see abstract) in order to help improve the biological integration of the ligament graft/cable member (see abstract, paragraph 7).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Dovesi to initiate a polymerization of a

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monomer solution in view of Brulez in order to help improve the biological integration of the ligament graft/cable member.

13. **Claims 54, 57, 139** are rejected under 35 U.S.C. 103(a) as being unpatentable over Dovesi et al US 2002/0165547 in view of Richelsoph US 5,976,187 and Sherman US 5,728,098.

Dovesi discloses the claimed invention as discussed above wherein the retention device is made out of a shape memory material but does not disclose the shape memory material is nitinol which is activated by heat transfer from bone.

Richelsoph discloses a retention device that it inserted into the body made out of nitinol, wherein the shape memory characteristics of the nitinol allows it to contract/bend and be easily inserted into the body and then when stimulated via heat, allows it to return to it's original shape and help anchor itself against bone (see Col 6 lines 40-50). Sherman teaches that nitinol has a transformational temperature range between room temperature and the human body (Col 4 lines 1-6), where heat from within the bone would interact with the nitinol.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the shape memory material of Dovesi to include nitinol in view of Richelsoph because the shape memory characteristics of the nitinol allows to change shape to be easily inserted into the body and when stimulated via heat, allows it to return to it's original shape and help anchor itself against bone, wherein when activated/expanded the retention device can contact the recess in the bone and cable

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member. It would have also been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination of Dovesi and Richelsoph that heat can be transferred from bone in view of Sherman because nitinol is a known shape memory material with a transformational temperature range between room temperature and the human body.

14. **Claims 140-141** are rejected under 35 U.S.C. 103(a) as being unpatentable over Dovesi et al US 2002/0165547, Richelsoph US 5,976,187 and Sherman US 5,728,098, as applied to claims 54, 139, above, and in further view of Boneau US 5,879,382.

The combination of Dovesi, Richelsoph and Sherman disclose the invention as discussed above but does not disclose, flooding the retention device with a liquid bath.

Boneau discloses a device made out of nitinol that is activated/ expanded by the use of heated fluids to cause expansion (see Col 2 lines 46-55).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination of combination of Dovesi, Richelsoph and Sherman to use a liquid bath in view of Boneau because it applies a known technique to a known device ready for improvement to yield predictable results of helping expand a shape memory material such as nitinol. The examiner notes that heat from the bath and body heat from the bone would activate the shape memory material.

### ***Conclusion***

The prior art made of record and relied upon is considered pertinent to the applicant's disclosure. See PTO-892 for art cited of interest.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAN CHRISTOPHER MERENE whose telephone number is (571)270-5032. The examiner can normally be reached on 8 am - 6pm Mon-Thurs, alt Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jan Christopher Merene/

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733